K060620

AUG 1 1 2006

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46256
(317) 521-2000

Contact Person: Scott Thiel / Luann Ochs

Date Prepared: August 3, 2006

2) Device name

Proprietary name: ACCU-CHEK® Aviva Test Strips

Common name: Whole blood glucose test system

Classification name: 75, LFR, Glucose Dehydrogenase, glucose

3) Predicate device

The Roche Diagnostics ACCU-CHEK Aviva system cleared under K043474 on April 27, 2005.

4) Device Description

The ACCU-CHEK Aviva Test Strips are stored within a desiccated vial. A test strip is removed from the vial and inserted into the meter. Upon insertion, the meter is activated. Blood is applied to the end of the test strip, and a glucose result is reported.

The test principle is:

Blood from the test site works with the chemicals in the test strip to make a small electrical current in the test strip. The meter reads the current and gives a blood glucose results.

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5) Intended use

The ACCU-CHEK Aviva Test Strips are used with the ACCU-CHEK Aviva meter. The ACCU-CHEK Aviva system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

Professionals may use the test strips to test capillary, venous, arterial, and neonate samples; home use is limited to capillary whole blood testing.

6) Similarities to predicate device

The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modifications.

Feature/Claim	Detail
Intended Use	Both systems are intended for testing glucose in whole blood by persons with diabetes or by health care professionals in the home or in health care facilities.
Closed System	Each system's test strips and controls are designed to be used only with that system.
Test Principle	Chemicals in the test strip make a small electric current in the test strip when dosed with a sample. The meter reads the current and gives a blood sugar result.
Test Strip storage conditions	Store the test strips at room temperature (less than 90°F); do not freeze.
Quality control procedures	User is directed to perform quality control testing: when the cap is left off the vial of test strips, when a new vial is opened, if the meter is dropped, if the result does not agree with the way the user feels, whenever the user wishes to check the performance of the system.
Altitude	10,150 feet
Reportable range	10 – 600 mg/dL
Warnings and precautions	Both systems are for *in vitro* diagnostic use only.
Active reagent composition	Glucose dehydrogenase
Monitor coding process	Both systems use a code key, included in the test strip vial, inserted into the meter.
Test strip packaging	Both systems provide test strips in a desiccated vial.
Identification of control solutions	Both systems automatically distinguish control solutions from whole blood samples.

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6) Similarities to predicate device, cont.

Feature/Claim	Detail
Test sample volume	0.6 µL
Test time	5 seconds
Expiration	In addition to information included in labeling, the code key contains expiration date of associated test strips. System informs user when code key has expired.
Test strip technology	The system utilizes both AC/DC electrical impedance information.
Labeling instructions regarding expected results	The normal fasting blood glucose range for an adult without diabetes is 74 – 106 mg/dL. Two hours after meals, the blood glucose range for an adult without diabetes is less than 140 mg/dL. For people with diabetes: consult your doctor for the blood glucose range appropriate for you.

6) Difference to predicate device

Topic	ACCU-CHEK Aviva Pro Test Strips	ACCU-CHEK Aviva
Sample Types	Whole blood (capillary, venous, arterial, and neonate)	Whole blood samples (capillary and venous)
Hematocrit	10 – 70%	20 – 70%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Scott Thiel, MT(ASCP), MBA
Regulatory Affairs Program Principal
Roche Diagnostics, Inc.
9115 Hague Road
Indianapolis, IN 46250-0416

AUG 11 2006

Re: k060620
Trade/Device Name: ACCU-CHEK® Aviva Test Strips
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR, NBW
Dated: July 24, 2006
Received: July 25, 2006

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060620

Device Name: ACCU-CHEK® Aviva Test Strips

Indications For Use:

The ACCU-CHEK Aviva Test Strips are used with the ACCU-CHEK Aviva meter. The ACCU-CHEK Aviva test system is designed to quantitatively measure the concentration of glucose for monitoring glucose in the home or in health care facilities. Testing sites include traditional fingertip site along with palm, forearm, upper arm, thigh, and calf.

Professionals may use the test strips to test capillary, venous, arterial, and neonatal blood; home use is limited to capillary whole blood testing.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Sign-Off

Office of In Vitro Diagnostic Device Evaluation

510(k) K060620